

Remarks

Claims 1-11 were pending in the application, with claims 9-11 withdrawn as directed to a non-elected invention. Claims 1 and 5-7 are amended herein, and claims 9-11 are canceled without prejudice. No new matter is added. Therefore, after entry of this Amendment, **claims 1-8** are pending in this application. Consideration of the pending claims is requested.

Support for the amendments to the claims is found throughout the specification, for example:

Claim 1 and 6: page 9, lines 23-26; page 19, lines 29-31.

Claims 5 and 7 are amended to correct typographical errors.

Request for Acknowledgement of Cited References

Applicants thank the Examiner for considering the Information Disclosure Statements (IDS) filed on July 27, 2006 and April 9, 2007. Applicants note that the references cited on pages 2-5 of the IDS filed on April 9, 2007 were not considered. A copy of the partially signed Form 1449 is provided herewith. Applicants respectfully request that the Examiner acknowledge that these references have been considered by returning a fully signed copy of the form 1449 with the next action.

Claim Objections

Claim 5 is objected to for the absence of a space between “Claim” and “1.” Claim 5 is amended herein to correct this typographical error.

Claim Rejections – 35 U.S.C. § 112

Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Applicants request reconsideration.

Claims 1 and 6, and dependent claims 2-5, 7, and 8 are rejected as allegedly indefinite in the recitation of “or an ortholog thereof” with respect to SEQ ID NO: 2. Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have removed

reference to the term “ortholog” from independent claims 1 and 6, thereby making this rejection moot.

Claims 1 and 6, and dependent claims 2-5, 7, and 8 are also rejected as allegedly indefinite in the recitation of “high oil phenotype relative to control plants” and “altered oil content phenotype relative to control plants” as it is allegedly unclear what is encompassed by the term “control plant.” Applicants assert that the term “control plant” is clear and definite to one of skill in the art. However, solely to expedite prosecution, claims 1 and 6 are amended herein to recite “. . . a plant of the same species that does not comprise the plant transformation vector...” Applicants submit that by this amendment, the nature of the “control plants” is sufficiently definite. Applicants request that this rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

Claims 1 and 6, and dependent claims 2-5, 7, and 8 are also rejected as allegedly indefinite in what would be considered “high oil” or “altered oil.” Applicants assert that these terms are clear and definite to one of skill in the art in light of the specification. “Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.” *Solomon v. Kimberly-Clark Corporation* 55 USPQ2d 1279, 1282, 216 F.3d 1372, 1378 (Fed. Cir. 2000). The specification at page 5, lines 29-33 specifically defines an altered oil content phenotype as “a statistically significant increase or decrease in overall oil content...as compared to the similar, but non-modified plant.” The specification further defines high oil phenotype as “an increase in overall oil content” (specification, page 5, line 33). Thus, the claims would clearly be understood by one of skill in the art in light of the specification, and Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 112

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office alleges that

“Applicants are claiming a genus of sequences. However, only one sequence has been provided.” (Office action, page 4, paragraph number 8). To the extent that this rejection might be maintained in view of the above amendments, Applicants request reconsideration.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384; 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [*i.e.*, “in the same words”] to be sufficient”).”

In the current instance, amended independent claims 1 and 6 recite “a plant transformation vector comprising . . . a nucleotide sequence that encodes a H10102 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO:2...” This language clearly and structurally describes the molecules that fall within the claimed subject matter.

Moreover, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the polypeptide sequence shown in SEQ ID NO:2; Applicants had also contemplated and provided explicit written description of polypeptides with at least 95% sequence identity to that sequence (for example, at page 9, lines 23-26). Further, the specification describes how to determine which sequences have at least 95% sequence identity to SEQ ID NO:2 (for example, at page 10, lines 7-19). Methods are also provided for determining which residues are highly conserved (for example, at page 10, lines 19-30); for the generation of

transgenic plants (at page 13, line 27 through page 16, line 30); and for determining if a plant (particularly a transgenic plant) produces a high oil producing phenotype (see Examples 1-2). Therefore, based on the teachings of the specification and the knowledge of one of skill in the art, a person of ordinary skill could envision sequences having at least 95% sequence identity to the sequence set forth in SEQ ID NO:2. The pending claims are thus sufficiently described by the specification, and Applicants request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-4 and 6-8 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jaworski *et al.* (U.S. Pat. No. 6,307,128). The Office alleges that Jaworski *et al.* “teach plants transformed with a nucleic acid...encoding a sequence that is identical to the HIO102 polypeptide of SEQ ID NO:2..., including methods of transformation, and a high oil phenotype or an altered oil content would be inherent in a plant comprising the same transgene.” Office action, page 6, paragraph number 12. Applicants assert that the claims as amended herein are neither explicitly nor inherently anticipated by Jaworski *et al.* and request reconsideration.

Jaworski *et al.* describe a sequence designated “EL2,” which is identical to SEQ ID NO:2 in the present application, and transgenic plants transformed with this sequence. The transgenic plants described by Jaworski *et al.* have “altered levels of very long chain fatty acids in tissues where the polynucleotide is expressed” (column 3, lines 6-8). Jaworski *et al.* also describe a method “for altering the levels of very long chain fatty acids in a plant” (column 3, lines 10-11). However, Jaworski *et al.* do not actually demonstrate production of a transgenic plant containing HIO102 (SEQ ID NO:2 of the present application). Instead, Jaworski *et al.* show that microsomal extracts from *yeast* expressing the EL2 sequence, when used in assays with 18:0 fatty acids, result in “a higher proportion of saturated VLCFAs” than microsomal extracts expressing FAE1 (column 15, lines 26-28). Similar results were shown in Tables 5 and 6 (columns 15-16). Thus, Jaworski *et al.* teach that the proportion of long chain fatty acids (LCFA) in a sample can be altered by EL2.

Amended claims 1 and 6 recite “wherein the polypeptide confers a high oil phenotype of increased oil content without a significant increase in long chain fatty acid components of seed oil relative to non-transgenic control plants...” The present application clearly states that both “[f]atty acid content and quality were examined” in transgenic plants expressing SEQ ID NO:2 and that “oil content is increased . . . without a significant increase in the long chain fatty acid components of the seed oil” (specification, page 19, lines 24-31). The specification describes high oil content in a plant line with altered expression of SEQ ID NO:2 (page 19, line 25). Submitted herewith is a Declaration under 37 C.F.R. § 1.132 signed by Dr. D. Ry Wagner (Declaration), which provides data describing the proportion of each of 16:0, 18:0, 18:1, 18:2, 18:3, 20:0, 20:1, 22:0, and 22:1 LCFAs as a percentage of the total fatty acid content, in control plants and transgenic plants overexpressing SEQ ID NO:2 (Declaration, paragraphs 4 and 5). None of the LCFA components measured in the seed oil of Applicants’ transgenic plants demonstrates a significant change in relative proportion, compared to oil composition of the control plants (Declaration, paragraph 5 and **Exhibit A**). Thus, the proportion of each of the LCFAs, and therefore the overall oil quality, in plants with altered expression of SEQ ID NO:2 remain unchanged compared to control plants. This contrasts with the altered profile shown in the yeast data in Jaworski *et al.*, and its teaching that the gene encoding SEQ ID NO:2 alters the fatty acid profile in oil by increasing the proportion of longer chain fatty acids (discussed above).

Further, in order to show inherency, a gap in a reference may be filled by extrinsic evidence, but the “evidence must make clear that the missing descriptive matter is **necessarily** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); MPEP § 2131.01, emphasis added.

The Office has presented no evidence that expression of HIO102 (SEQ ID NO:2 or sequences having at least 95% identity to SEQ ID NO:2) in transgenic plants necessarily results in a high oil phenotype of increased oil content without a significant increase in long chain fatty acid components of seed oil relative to non-transgenic control plants. In fact, Jaworski *et al.* do not demonstrate the effect of HIO102 in transgenic plants or plant cells; rather they show the effect in yeast, which are single-celled fungi. Jaworski *et al.* do not provide any data for

expression of HIO102 in plants, but extrapolates from the observations from yeast metabolism. In contrast, the present application demonstrates that a transgenic plant expressing HIO102 (SEQ ID NO:2) has a high oil phenotype, and further, that there is no increase in the proportion of long chain fatty acids. Thus, it is clear that expression of HIO102 in a transgenic plant does not necessarily result in the phenotype described by Jaworski *et al.* (that is, a transgenic plant with altered levels of long chain fatty acids), and the claims are not anticipated by this reference.

Applicants further emphasize with respect to the pending method claims (claims 6-8) that the present application teaches a method of “producing a plant with a high oil phenotype...” The specification describes a high oil phenotype as “an increase in overall oil content” (specification, page 5, line 33). Thus, the claimed method is directed to producing a plant with increased overall oil content, and particularly without disproportionately increasing the long chain fatty acid components of seed oil. In contrast, Jaworski *et al.* teach a method “for altering the levels of very long chain fatty acids in a plant” (column 3, lines 10-11). In fact, Jaworski *et al.* teach away from the claimed invention, which as recited in amended claims 1 and 6, produces a plant with a “high oil phenotype of increased oil content without a significant increase in long chain fatty acid components of seed oil...” Therefore, Jaworski *et al.* do not explicitly or inherently anticipate the claimed invention.

Based on the foregoing, Applicants assert that the pending claims are not anticipated, either explicitly or inherently, by Jaworski *et al.* and respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Claim Rejections – 35 U.S.C. § 103

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Jaworski *et al.* The Office asserts that Jaworski *et al.* teach plants transformed with a sequence identical to HIO102 (SEQ ID NO:2), methods of transformation, and a that a high oil phenotype or an altered oil content would be inherent. The Office further asserts that Jaworski *et al.* also teach that the sequence encodes a beta-ketoacyl synthase involved in synthesis of long chain fatty acids and methods of analyzing fatty acid composition. (Office action, page 7, paragraph number 17)

The Office then asserts that it would be obvious to one of ordinary skill to recover oil from the transgenic plants prior to analyzing fatty acids. (Office action, page 8, paragraph number 19)

As an initial matter, Applicants point out that claims 1-4 are directed to a transgenic plant having a high oil phenotype. These claims do not include any limitation requiring recovery of oil from the transgenic plant. Therefore, whether or not it would be obvious to one of ordinary skill to recover oil from such plants is not ground for rejection of these claims. Further, claim 6 is directed to a method of producing a high oil phenotype in a plant by “introducing into progenitor cells of the plant a plant transformation vector comprising a nucleotide sequence that encodes a HIO102 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide confers a high oil phenotype of increased oil content without a significant increase in long chain fatty acid components of seed oil relative to a plant of the same species not comprising the plant transformation vector, and b) growing the transformed progenitor cells to produce a transgenic plant...” This claim (and dependent claims 7 and 8) does not require recovery of oil as a limitation of the claim, and thus the assertion by the Office that it would be obvious to recover the oil is not ground for rejection of claims 6-8.

Claim 5 is the only pending claim which includes recovering oil from a transgenic plant. With respect to claim 5 (and in fact all of claims 1-8), Applicants assert that Jaworski *et al.* **teach away** from production of a transgenic plant wherein expression of SEQ ID NO:2 (or a sequence having at least 95% identity to SEQ ID NO:2) confers a high oil phenotype of increased oil content without a significant increase in the proportion of long chain fatty acid components of seed oil. As discussed above, Jaworski *et al.* describe (hypothetical) transgenic plants expressing a sequence identical to SEQ ID NO:2 which have altered levels of very long chain fatty acids and provide data from yeast showing that expression of this polypeptide increases long chain fatty acids in microsomal extracts. In contrast, the present application (further supported by the Declaration submitted herewith) shows that expression of SEQ ID NO:2 in transgenic plants increases oil content without significantly increasing the proportion of long chain fatty acid components. As Jaworski *et al.* teach away from the claimed invention, it would clearly not be obvious to one of skill in the art to arrive at the claimed invention in light of Jaworski *et al.*

Based on the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully submit that the claims are now in condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned to arrange a telephonic interview prior to the preparation of any further written action.

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cc: Docketing